PHARMACY BOARD[657]

Adopted and Filed

Rule making related to temporary scheduling of cannabidiol drug products

The Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 124.201 and 124.201A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.201A.

Purpose and Summary

This rule making temporarily places into Schedule V of the Iowa Uniform Controlled Substances Act any drugs approved by the U.S. Food and Drug Administration (FDA) which contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols (THC).

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 24, 2018, as **ARC 4086C**. This rule making was also adopted and filed emergency and published in the Iowa Administrative Bulletin as **ARC 4085C** on the same date. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on January 9, 2019.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 6, 2019, at which time the Adopted and Filed Emergency amendment is hereby rescinded.

The following rule-making action is adopted:

Adopt the following **new** subrule 10.39(4):

10.39(4) Amend Iowa Code section 124.212 by adding the following new subsection "6":

6. Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

[Filed 1/10/19, effective 3/6/19] [Published 1/30/19]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/30/19.